EXHIBIT A

UNITED STATES DEPARTMENT OF JUSTICE

Drug Enforcement Administration

In the Matter of **Holiday CVS, L.L.C., d/b/a CVS/Pharmacy #00219**	**Docket No. 12-37**
Holiday CVS, L.L.C., d/b/a CVS/Pharmacy #05195	**Docket No. 12-38**

ORDER ON HEARING SCOPE AND GOVERNMENT MOTIONS REGARDING THE RESPONDENTS' EXPERTS

These proceedings were initiated by the Government on February 2, 2012, with individual Orders to Show Cause / Immediate Suspension of Registration Orders (OSC/ISO). The OSC/ISOs directed the Respondents to show cause why the Drug Enforcement Administration (DEA) Certificates of Registration (COR) that were previously issued to each Respondent should not be revoked, and that any pending renewal actions be denied. Additionally, the OSC/ISOs directed the immediate suspension of the Respondents' CORs, based upon the DEA Administrator's finding that continued registration during the pendency of these administrative proceedings would constitute an imminent danger to public health and safety. *See* 21 C.F.R. § 1301.36(e). The actions were consolidated without opposition on March 7, 2012.

On March 16, 2012, the United States District Court for the District of Columbia (Walton, J.) issued an order denying requests for relief sought there, including (but not limited to) a petition for a preliminary injunction to enjoin enforcement of that portion of the OSC/ISO which immediately suspended the Respondents' COR privileges pending the administrative adjudication of this matter on the merits. *Holiday C.V.S., L.L.C. v. Holder*, __ F. Supp.2d __, ___, 2012 WL 883123 (D.D.C. 2012).

On March 20, 2012, a Prehearing Ruling was issued by this tribunal. The Prehearing Ruling provided that "[e]xhibits provided after March 30, 2012, may not be admitted into evidence, absent a showing of good cause." Prehearing Ruling, at 3

(emphasis omitted). The Prehearing Ruling further directed that any motions or supplemental prehearing statements be filed on or before 2:00 p.m. EDT on March 30, 2012. Prehearing Ruling, at 4.

On March 30, 2012, the Respondents filed a Consolidated Supplemental Prehearing Statement (RSPHS) in which they identified two proposed expert witnesses in the field of pain management – Sunil J. Panchal, M.D., and Jeffrey A. Zipper, M.D. ("the Pain Experts"). Resp'ts Supp. PHS, at 5. The RSPHS also identified as proposed, but unenclosed, exhibits: (1) an "Expert report of Sunil Panchal, M.D.;"[1] and (2) a "Potential expert report of Jeffery A. Zipper M.D."[2] Resp'ts Supp. PHS, at 24-25. In this regard, the RSPHS sought "leave . . . to submit the expert report of Sunil J. Panchal, who was only recently retained as Respondents' pain management expert, on or before April 6, 2012." Resp'ts Supp. PHS, at 18. No such leave was requested for submission of the expert report of Dr. Zipper.

Respondent's Motion for Leave

On April 6, 2012, the Respondents filed a Motion to File Expert Reports ("Motion for Leave") of Sunil J. Panchal, M.D., and Jeffrey A. Zipper, M.D. Citing delays in retaining experts and obtaining the corresponding expert reports, the motion seeks leave to submit the reports of the as proposed exhibits. The Government opposes the Motion for Leave as untimely and based on the grounds set forth in its previously filed Motion to Strike Respondents' Pain Management Witnesses, discussed below. Government's Opposition to Respondents' Motion to File Expert Reports of Sunil J. Panchal, M.D., and Jeffrey A. Zipper, M.D. ("Government's Response"), at 1.

The Respondent has shown good cause for the late filing of the expert reports. Accordingly, the Motion for Leave is **GRANTED.** Consideration of the merits of the Motion to Strike will be discussed below.

Government Motion to Strike And Hearing Scope

The Administrative Procedure Act (APA) and the DEA regulations provide the presiding Administrative Law Judge with the authority to regulate the course of the hearing and simplify the issues to be decided in this litigation. 5 U.S.C. § 556(c); 21

[1] Prop. Resp't Ex. 66.
[2] Prop. Resp't Ex. 83.

C.F.R. § 1316.55. The DEA regulations and traditional practice provides for simplification of hearing issues at a prehearing conference, such as the one conducted in this matter on March 19, 2012 (Prehearing Conference). 21 C.F.R. § 1316.54(a). Although numerous issues were discussed with the parties during the course of the Prehearing Conference in an attempt to narrow and focus the issues amenable to hearing, the supplemental prehearing statements submitted by the parties make it clear that additional direction in this regard prior to the commencement of the hearing would be helpful. **Accordingly the issues that will be the subject of litigation in this matter will be refined as set forth in this order.**

On April 5, 2012, notwithstanding the reality that no evidence has been offered or admitted to the administrative record, the Government filed what it styled as a Motion to Strike Respondents' Pain Management Witnesses ("Motion to Strike").[3] In its Motion to Strike, the Government seeks the exclusion of testimony and expert reports prepared by the Pain Experts based upon the contention that such evidence would be irrelevant and immaterial. Specifically, the Government avers that these proceedings "d[o] not directly concern the practices of physicians who issue the prescriptions, the proper medical procedures to treat pain or the nature of the patient-physician relationship." Gov't Mot. to Strike at 2. The Respondents contend that that the Motion to Strike should be denied as untimely or, in the alternative, because the proposed evidence is admissible in these proceedings. Respondents' Opposition to Government's Motion to Strike Respondent's Pain Management Witnesses ("Respondents' Response"), at 1 n.1, 2.

As an initial matter, the Respondents contend that the Motion to Strike should be denied because the motion was filed after the March 30, 2012, deadline fixed by the Prehearing Ruling. Respondent's Response, at 1 n. 1. The Government submits that late filing should be excused because the issues raised by the Motion to Strike were not

[3] While the Government's Motion to Strike could correctly be denied based on the fact that it seeks to "strike" proposed testimony which has been neither offered or received into evidence, its filing raises significant issues, the consideration of which could facilitate proceedings that are more focused and productive. Thus, the Government's Motion will be considered as if it were styled as a motion *in limine*. While an *in limine* motion is a procedural tool that is customarily utilized to insulate the members of a jury from patently inadmissible evidence that would create an unacceptable risk of unfair prejudice, such a motion can also properly be employed to prevent an unreasonable expenditure of litigation time and effort considering evidence that could and should be eliminated out of hand.

identifiable until service of the RSPHS on the Government on March 30, 2012.

The Respondents Consolidated Prehearing Statement, filed on March 19, 2012, noticed a "Proposed Pain Management Expert," who would testify regarding "chronic pain treatment and palliative care," as well as "[p]ain medications, including potential treatment options, therapeutic regimens and prescription volumes that are consistent with legitimate medical practice." Respondents' Consolidated Prehearing Statement (RCPHS), at 44-45. Thus, the Respondents contend that, contrary to the Government's position, the issues raised in the Motion to Strike were identifiable no later than March 19, 2012. Respondents' Response, at 1 n. 1.

At the Prehearing Conference, the Respondents were informed that the notice provided by the "Proposed Pain Management Expert" was insufficient to allow for expert testimony and that, to the extent they intended to call a pain management expert, they were required to provide adequate notice on or before March 30, 2012. Insofar as the RCPHS did not provide sufficient notice to allow for the testimony of a pain management expert, it cannot be said that the Government was on notice of the need to file a motion seeking exclusion of such testimony until the service of the RSPHS on March 30, 2012. Therefore, the Government has shown good cause for the filing of the Motion to Strike beyond the March 30, 2012, deadline.

Turning to the merits of the Motion to Strike, the Government contends that the exclusion of the testimony and reports of the Pain Experts is warranted because such evidence is irrelevant and immaterial to the above actions. In particular, the Government contends that "[t]he standard to be examined in this case is what pharmacies – not doctors – are required to do to scrutinize the legitimacy of prescriptions." Motion to Strike, at 2.

Administrative proceedings before the DEA, including the procedures for the admission and exclusion of evidence therein, are governed by the APA, applicable provisions of the Controlled Substances Act (CSA) and its implementing regulations, as well as the Due Process Clause of the United States Constitution. The APA provides that "[a]ny oral or documentary evidence may be received, but the agency as a matter of policy shall provide for the exclusion of irrelevant, immaterial, or unduly repetitious evidence." 5 U.S.C. § 556(d). The implementing DEA regulations provide that the Administrative Law Judge "shall admit only evidence that is competent, relevant, material and not unduly

repetitious." 21 C.F.R. § 1316.59. Under the APA, "the proponent of a[n] . . . order has the burden of proof."[4] 5 U.S.C. § 556(d); *see also* 21 C.F.R. § 1316.56 ("[a]t any hearing, the proponent for the issuance, amendment, or repeal of any rule shall have the burden of proof."). Thus, the Government, as the moving party, is encumbered with the burden of proof to show that the proposed evidence is irrelevant, immaterial, incompetent, or unduly repetitious. *Id.*

Generally speaking, under common law, evidence is relevant when it has "a tendency to make the proposition for which it is offered more probably so than if the evidence had not been offered." *U.S. v. Dunn*, 805 F.2d 1275, 1281 (6th Cir. 1986). In order for the evidence to be material, "[t]he proposition to be proved [must be] within the range of litigated matters in controversy." *Id.* The test for relevancy under the Federal Rules of Evidence has combined these two tests by providing that "[e]vidence is relevant if: (a) it has a tendency to make a fact more or less probable than it would be without the evidence; and (b) the fact is of consequence in determining the action." Fed. R. Evid.. 401. "Competency in evidence law may be defined as the presence of those characteristics and the absence of those disabilities that render a witness legally qualified to testify in court." *Donovan v. Sears Roebuck & Co.*, 849 F.Supp. 86 (D.Mass. 1994) (quoting 27 Wright and Gold, Federal Practice and Procedure, § 6002, pg 18 (1990)). Evidence is unduly repetitious when its probative value is outweighed by the degree of repetition. *Robert Raymond Reppy, D.O.*, 76 Fed. Reg. 61154, 61160 (2011) (weighing degree of repetition against probative value).

Pursuant to 21 U.S.C. § 824(a)(4) (2006), the Administrator[5] is permitted to revoke a COR if persuaded that the registrant "has committed such acts as would render . . . registration under section 823 . . . inconsistent with the public interest . . . ." The following factors have been provided by Congress in determining "the public interest":

(1) The recommendation of the appropriate State licensing board or professional disciplinary authority.

(2) The [registrant's] experience in dispensing, or conducting research with respect to controlled substances.

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[4] The APA definition of "order" includes "the whole *or part* of a final disposition . . ." 5 U.S.C. § 551(6) (emphasis supplied).

[5] This authority has been delegated pursuant to 28 C.F.R. §§ 0.100(b) and 0.104 (2010).

(3) The [registrant's] conviction record under Federal or State laws relating to the manufacture, distribution, or dispensing of controlled substances.

(4) Compliance with applicable State, Federal or local laws relating to controlled substances.

(5) Such other conduct which may threaten the public health and safety.

21 U.S.C. § 823(f) (2006 & Supp. III 2010).

In an action to revoke a registrant's COR, the DEA has the burden of proving that the requirements for revocation are satisfied. 21 C.F.R. § 1301.44(e) (2011). The Government may sustain its burden by showing that the Respondent has committed acts inconsistent with the public interest. *Jeri Hassman, M.D.*, 75 Fed. Reg. 8194, 8235-36 (2010). Once DEA has made its *prima facie* case for revocation of the registrant's COR, the burden of production then shifts to the Respondent to present sufficient mitigating evidence to assure the Administrator that he or she can be entrusted with the responsibility commensurate with such a registration. *Steven M. Abbadessa, D.O.*, 74 Fed. Reg. 10077, 10078, 10081 (2009); *Medicine Shoppe-Jonesborough*, 73 Fed. Reg. 364, 387 (2008); *Samuel S. Jackson, D.D.S.*, 72 Fed. Reg. 23848, 23853 (2007);. *Morall v. DEA*, 412 F.3d 165, 174 (D.C. Cir. 2005); *Humphreys v. DEA*, 96 F.3d 658, 661 (3rd Cir. 1996); *Shatz v. U.S. Dept. of Justice*, 873 F.2d 1089, 1091 (8th Cir. 1989); *Thomas E. Johnston*, 45 Fed. Reg. 72311, 72312 (1980). "[T]o rebut the Government's *prima facie* case, [the Respondent] is required not only to accept responsibility for [the established] misconduct, but also to demonstrate what corrective measures [have been] undertaken to prevent the reoccurrence of similar acts." *Jeri Hassman, M.D.*, 75 Fed. Reg. at 8236. Normal hardships to the practitioner and even to the surrounding community that are attendant upon the lack of registration are not relevant considerations. *Abbadessa*, 74 Fed. Reg. at 10078; *see also Gregory D. Owens, D.D.S.*, 74 Fed. Reg. 36751, 36757 (2009).

A careful reading of the OSC/ISOs issued by the Government reveals, in essence, four factual allegations offered in support of the revocation of the Respondents' CORs: (1) that the amounts of oxycodone purchased by the Respondents from 2008 through 2011 showed significant increases and "considerably surpassed the amount of oxycodone ordinarily purchased by a retail pharmacy"; (2) that "DEA and the State of Florida have taken criminal, civil or administrative action against [numerous] physicians whose

customers fill their controlled substance prescriptions at [the Respondent pharmacies] for activities resulting in the diversion of controlled substances . . . ."; (3) that the Respondents have "failed in carrying out [their] responsibilities as [] DEA registrant[s]" as evidenced by alleged admissions by the pharmacists-in-charge of the respective pharmacies, and after specific guidance provided to them by DEA officials; and, (4) that the Respondents have "failed to maintain effective controls against diversion of controlled substances in violation of 21 C.F.R. § 1301.76."

Addressing the final factual allegation first, 21 C.F.R. § 1301.76 imposes the following security requirements on a pharmacy: (1) a pharmacy may not employ as an agent or employee, "any person who has been convicted of a felony offense relating to controlled substances or who, at any time, had an application for registration with the DEA denied, had a DEA registration revoked or has surrendered a DEA registration for cause;" (2) a pharmacy must notify the Field Division office in the area of any theft or loss of controlled substances; (3) when distributing controlled substances (defined as delivering to a non-ultimate user), a pharmacy must comply with certain additional security requirements; and (4) when filling prescriptions by mail, a pharmacy must comply with certain additional security requirements. Agency precedent has long held that in DEA administrative proceedings that "the parameters of the hearing are determined by the prehearing statements." *CBS Wholesale Distribs.*, 74 Fed. Reg. 36746, 36750 (2009) (citing *Darrel Risner, D.M.D.*, 61 Fed. Reg. 728, 730 (1996)); *see also Roy E. Berkowitz, M.D.*, 74 Fed. Reg. 36758, 36759-60 (2009) ("pleadings in administrative proceedings are not judged by the standards applied to an indictment at common law" and "the rules governing DEA hearings do not require the formality of amending a show cause order to comply with the evidence"). Notwithstanding the OSC/ISO allegation related to the "effective controls" provision in the regulations, the Government's prehearing statement sets forth no factual underpinnings to support a violation of this provision. Accordingly, on the current procedural posture of the record, no evidence can be received at the hearing on this issue.

Turning to the factual allegation in the OSC/ISOs that charge that the Respondents have purchased increasing amounts of oxycodone and have purchased it in numbers that "considerably surpassed the amount of oxycodone ordinarily purchased by

a retail pharmacy," such allegations allege no misconduct that can support adverse administrative action against the Respondents' CORs. While the Agency, in its administrative precedent, has not shied away from examining numbers in evaluating a pharmacy registrant's execution of his, her, or its corresponding responsibility, those evaluations have been limited to an examination of whether numbers associated with whether a particular prescription-issuing physician has created an obligation to resolve a potential issue related to the legitimacy of controlled substance prescriptions. *See, e.g., Liddy's Pharmacy, L.L.C.*, 76 Fed. Reg. 48887 (2011) (volume and locations made valid physician-patient relationship sufficiently unlikely to create a duty to resolve the conflict); *Ralph J. Bertolino, d/b/a/ Ralph J. Bertolino Pharmacy*, 55 Fed. Reg. 4729, 4730 (1990) (to same effect); *Trinity Health Care Corp., d/b/a/ Oviedo Discount Pharmacy*, 72 Fed. Reg. 30849, 30854 (2007) (to same effect). However, sheer numbers of prescriptions issued by a registrant, compared to other registrants similarly situated, has never been (and could not logically be) a justification, standing alone, for an adverse administrative action against a COR unless it was tied to the abrogation of a legally-imposed responsibility. To be sure, this factual allegation related to volume was appropriately set forth in the charging document for consideration on issues related to the immediate suspension, and factored into the decision issued by the District Court relative to the ISO preliminary injunction litigation in its evaluation of the Administrator's finding imminent danger to the public health and safety.[6] Thus, this allegation supports no basis for revocation under the facts as alleged by the Government within the constraints of what is alleged in its Prehearing Statements. This tribunal has no jurisdiction to adjudicate the merits of the immediate suspension action taken by the Administrator. *See* 21 U.S.C. § 824(d); 21 C.F.R. § 1301.36(e).

Accordingly, as explained below, absent a nexus to a red flag of diversion, proposed testimony and exhibits noticed by the Government designed to demonstrate aggregate numbers and relative aggregate numbers of controlled substance prescriptions dispensed by the Respondents do not constitute relevant evidence as proffered by the Government and will not be received into the record. In particular, while the proposed

[6] *Holiday C.V.S., L.L.C. v. Holder*, __ F. Supp 2d __, __, 2012 WL 883123 (D.D.C. 2012).

testimony of Unit Chief Kyle Wright that the "significant increase in purchases of oxycodone can be an indicator of diversion and abuse," may bear some background relevance to explain the course of the investigation and why the Respondents may have been targeted for scrutiny, as proffered, it would shed no light on the extent to which the registrants here executed their corresponding responsibility, and thus, would provide no relevant evidence at the hearing.[7] Naturally, Respondents' proposed evidence which has been noticed to rebut such evidence (Paul Greenberg) is irrelevant as well.

Similarly, there is no authority, either in Agency precedent or the relevant regulations, which would support the Government's OSC/ISO allegation that revocation is warranted merely because adverse administrative and criminal actions were obtained against physicians whose prescriptions were dispensed by the Respondents' pharmacies. Accordingly, the proposed evidence noticed by the Government from Diversion Program Manager Susan Langston regarding medical practitioners who have been the subject of adverse criminal and/or administrative action will only be admitted to the extent these practitioners are linked to specific alleged actions on the part of the Respondents that reflect on a failure to properly execute their corresponding responsibility, as that term is defined under the regulations and Agency precedent (*e.g.*, controlled substances dispensed by a registrant on a prescription written by a physician who has lost the privileges to legally do so). In like fashion, the same principle will be applied to the noticed testimony of Group Supervisor Ruth Carter regarding the purported acknowledgement to her by a pharmacist employed by one of the Respondents that he was aware of an *arrest*[8] of a physician.

Upon review of the charging documents filed by (and drafted by) the Government in this matter, the only actionable factual allegation asserted which is amenable to determination on this record, is that the Respondents have been delinquent in executing their corresponding responsibility under the regulations. More specifically, the Government's Consolidated Prehearing Statement read in conjunction with the

[7] Agency precedent has been clear that "under the substantial evidence test, the evidence must 'do more than create a suspicion of the existence of the fact to be established.'" *Alvin Darby, M.D.*, 75 Fed. Reg. 26993, 26999, n.31 (2010) (citing *NLRB v. Columbian Enameling & Stamping Co.*, 306 U.S. 292, 300 (1939); *see also Paul Weir Battershell, N.P.*, 76 Fed. Reg. 44359, 44367 (2011).

[8] The Agency has held that the filing of an indictment, standing alone, is not proof of the facts alleged therein. *Battershell*, 76 Fed. Reg. at 44364 n.16.

corresponding OSC/ISOs implicate consideration of Factors Two and Four only.

Under the regulations, "[t]he responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a *corresponding responsibility* rests with the pharmacist who fills the prescription." 21 C.F.R. § 1306.04(a) (emphasis supplied). Put simply, a pharmacist has a "corresponding responsibility under Federal law to dispense only lawful prescriptions." *Liddy's Pharmacy*, 76 Fed. Reg. at 48895. The corresponding responsibility to ensure the dispensing of valid prescriptions extends to the pharmacy itself. *See* Drug Enforcement Administration, *Issuance of Multiple Prescriptions for Schedule II Controlled Substances*, 72 Fed. Reg. 64921, 69424 (2007) (referring to a *pharmacy's* corresponding responsibility); *see also* Drug Enforcement Administration, *Role of Authorized Agents in Communicating Controlled Substance Prescriptions to Pharmacies*, 75 Fed. Reg. 61613, 61617 (2010) (Referring to a pharmacies "corresponding responsibility regarding the dispensing of controlled substances."); *EZRX, LLC*, 69 Fed. Reg. 63178, 63181 (2004) ("DEA has issued orders to show cause and subsequently revoked the DEA registrations of pharmacies which failed to fulfill *their* corresponding responsibility in Internet prescribing operations.") (emphasis added). Settled Agency precedent has interpreted this corresponding responsibility as prohibiting the filling of a prescription where the pharmacist or pharmacy "knows or has reason to know" that the prescription is invalid.[9] *Bob's Pharmacy & Diabetic Supplies*, 74 Fed. Reg. 19599, 19601 (2009) (citing *Medicine Shoppe-Jonesborough*, 73 Fed. Reg.at 381 (quoting *Medic-Aid Pharmacy*, 55 Fed. Reg. 30043, 30044 (1990))); *See also United Prescription Services, Inc.*, 72 Fed. Reg. 50397, 50407-08 (2007) (Finding violation of corresponding responsibility where pharmacy "had ample reason to know" that the practitioner was not acting in the usual course of professional practice).

[9] In addition to the foregoing, under Florida law a pharmacist will be subject to discipline if he or she "dispens[es] any medicinal drug based upon a communication that purports to be a prescription . . . . when the pharmacist knows or has reason to believe that the purported prescription[9] is not based upon a valid practitioner-patient relationship." Fla. Stat. § 465.016(1)(s). In *Trinity Health Care Corp.*, 72 Fed. Reg. at 30854, the Agency acknowledged that the Florida state standard reflects essentially the same standard present in the DEA regulations which makes it unlawful to for a pharmacy registrant to intentionally look the other way "to avoid [actual] knowledge of the real purpose of [an illegitimate] prescription." *Bertolino*, 55 Fed. Reg. at 4730.

The Agency's precedent has carefully and consistently circumscribed the parameters of the term "corresponding responsibility" in the regulations "as prohibiting a pharmacist from filling a prescription for a controlled substance when he either knows or has reason to know that the prescription was not written for a legitimate medical purpose," and has been equally consistent in its admonishment that "[w]hen prescriptions are clearly not issued for legitimate medical purposes, a pharmacist may not intentionally close his eyes and thereby avoid [actual] knowledge of the real purpose of the prescription." *Sun & Lake Pharmacy, Inc.*, 76 Fed. Reg. 24523, 24530 (2011); *Liddy's Pharmacy, L.L.C.*, 76 Fed. Reg. at 48895; *East Main Street Pharmacy*, 75 Fed. Reg. 66149, 66163 (2010); *Lincoln Pharmacy*, 75 Fed. Reg. 65667, 65668 (2010); *Bob's Pharmacy*, 74 Fed. Reg. at 19601. Over the years, the Agency's view of the scope of conduct encompassed by the corresponding responsibility assigned by the regulations to its pharmacy registrants has not expanded or contracted.

The Agency does not require omniscience. *Carlos Gonzalez*, 76 Fed. Reg. 63118, 63142 (2011) (citing *Holloway Distrib.*, 72 Fed. Reg. 42118, 42124 (2007)). However, when the circumstances surrounding the presentation of a prescription would give rise to suspicion in a "reasonable professional," there is a duty to "question the prescription[]." *Bertolino*, 55 Fed. Reg. at 4730. Though initially framed as a "reasonable professional" standard, the Agency has considered the duty to discharge the corresponding responsibility by evaluating the circumstances in light of what would be considered suspicious by a "reasonable pharmacist." *East Main Street Pharmacy*, 75 Fed. Reg. at 66165; *see also Winn's Pharmacy*, 56 Fed. Reg. 52559, 52561 (1991). Accordingly, a pharmacist or pharmacy may not dispense a prescription in the face of a red flag (i.e., a circumstance that does or should raise a reasonable suspicion as to the validity of a prescription) unless he or it takes steps to resolve the red flag and ensure that the prescription is valid. *Id.* Because Agency precedent limits the corresponding responsibility to circumstances which are known or should have been known, *Sun & Lake Pharmacy, Inc.*, 76 Fed. Reg. at 24530, it follows that, to show a violation of a corresponding responsibility, the Government must establish that: (1) the Respondent dispensed a controlled substance; (2) a red flag was or should have been recognized at or before the time the controlled substance was dispensed; and (3) the question created by

the red flag was not resolved conclusively prior to the dispensing of the controlled substance. *See Sun & Lake Pharmacy*, 76 Fed. Reg. at 24532 (Finding that pharmacy violated corresponding responsibility where it took no steps to resolve red flags prior to dispensing controlled substances.). The steps necessary to resolve the red flag conclusively will *perforce* be influenced by the nature of the circumstances giving rise to the red flag.

When considering whether a pharmacy has violated its corresponding responsibility, the Agency considers whether the *entity*, not the pharmacist, can be charged with the requisite knowledge. *See United Prescription Services*, 72 Fed. Reg. 50397, 50407 (Respondent pharmacy violated corresponding responsibility because "an *entity* which voluntarily engages in commerce [to] other States is properly charged with knowledge of the laws regarding the practice of medicine in those States."). Knowledge obtained by the pharmacists and other employees acting within the scope of their employment may be imputed to the pharmacy itself. *See U.S. v. One Parcel of Land*, 965 F.2d 311, 316 (7th Cir.1992) ("Only knowledge obtained by corporate employees acting with the scope of their employment is imputed to the corporation.").

Regarding the Government's Motion to Strike, the Respondents have noticed their intention to elicit testimony and offer reports of the Pain Experts to rebut the Government's allegations that the following circumstances constitute red flags sufficient to trigger a duty to inquire under the corresponding responsibility: (1) high dosage units for controlled substances; (2) standardization by physicians in the type, strength and amount of medicines prescribed; (3) cash payments by patients at the pharmacy; and (4) large distances between a patient, the pharmacy and the prescriber. Respondents' Response, at 2-3. Based on the proffered expert reports, it appears that the Respondents seek to elicit the Pain Experts' views that the circumstances the Government alleges to be red flags should not be considered red flags because "many" patients with legitimate prescriptions may display the allegedly suspicious circumstances with benign justifications.

Putting aside issues of cumulativeness,[10] this proposed evidence misses the point. An evaluation of whether a pharmacy registrant has adequately discharged the

[10] 21 C.F.R. § 1316.59(a).

corresponding responsibility under the regulations is not dependent upon whether a red flag issue is conceivably resolvable; but whether a red flag was recognizable and ignored prior to or at the time a controlled substance prescription is filled.[11] *Sun & Lake Pharmacy, Inc.*, 76 Fed. Reg. at 24530. Simply put, evidence that certain alleged red flags are not dispositive indicators of prescription illegitimacy is not relevant to whether the alleged red flags would raise a suspicion regarding the validity of a prescription in a reasonable professional, or whether such a red flag was ignored.[12] It is certainly conceivable that an invalid prescription that raised no red flags could be filled without delinquent conduct on the part of the pharmacy registrant, and equally true that a valid prescription that implicated unresolved red flags (that would have been subject to benign explanation) could constitute a failure to properly attend to a registrant's corresponding responsibility.

Additionally, the Respondents have noticed their intention to offer testimony from the Pain Experts in an effort to rebut assertions by the Government's purported expert regarding the proper dosing for Oxycontin and addressing what is essentially styled as an illogical juxtaposition of the pharmacist's corresponding responsibility against the better-trained judgment of a treating physician's prescription, issued with the benefit of patient histories, examinations, and tests. As discussed below, the portion of the Government's expert's report dealing with the dosing of Oxycontin is irrelevant and will not be considered. Accordingly, no rebuttal is needed. As to the interplay of pharmacy and physician opinions, Agency precedent recognizes that

> Federal law imposes separate and independent duties on the prescriber and the pharmacist. More specifically, the prescriber must act within the usual course of professional practice and have a legitimate medial purpose to lawfully issue a controlled-substance prescriptions. 21 C.F.R. 1306.04(a). As the Supreme Court and numerous Federal courts have made plain, to lawfully prescribe a controlled substance the physician must act "in accordance with a standard of medical

[11] Indeed, even if it were conceded, *arguendo*, that many or even most red flags address issues that could be resolved in favor of dispensing, it would not relieve a registrant of his duty to resolve prior to dispensing a controlled substance.

[12] That the Pain Experts possess no experience, training or knowledge regarding the identification of illegitimate prescriptions in a pharmacy setting is an additional reason (but not the principal reason) for rejecting the proffered testimony. *See* Fed. R. Evid. 702 (Qualification of expert may be made based on knowledge, skill, experience, training or education.). Stated differently, although the proffered witnesses are likely qualified to resolve a red flag if queried on the issue by a pharmacist, there is no proffered qualification that would support the competence of these witnesses to render an opinion on what a pharmacist should be monitoring for, at or before a controlled-substance prescription is dispensed.

> practice generally recognized and accepted in the United States." *United States v. Moore*, 423 U.S. 122, 138-39 (1975); *see also United States v. Smith*, 573 F.3d 639, 647-48 (8th Cir. 2009); *United States v. Merrill*, 513 F.3d 1293, 1306 (11th Cir. 2008). By contrast, a "pharmacist is not required to . . . practice medicine." *United States v. Hayes*, 595 F.2d 258, 261 (5th Cir. 1979). What is required of [a pharmacist] is the responsibility not to fill an order that purports to be a prescription but is not a prescription within the meaning of the statute because he knows [or has reason to know] that the issuing practitioner issued it outside the scope of medical practice." *Id.* at 261. As the Fifth Circuit has further explained, "a pharmacist can know that prescriptions are issued for no legitimate medical purpose without his needing to show anything about medical science." *Id.* at 261 n.6; *see also United States v. Henry*, 727 F.2d 1373, 1379, (5th Cir. 1984) (applying "reason to believe" standard to pharmacist); *United States v. Seeling*, 622 F.2d 207, 213 (6th Cir. 1980) (upholding use of deliberate ignorance instruction in prosecution of pharmacist.)

East Main Street Pharmacy, 75 Fed. Reg. at 66157, n.30. The regulations do not put the judgment of the pharmacist and the prescribing physician in conflict. The respective responsibilities of these dual professionals in their roles as registrants are distinct. Under Federal law, a pharmacist is not required to fill a prescription merely because a physician has authorized a prescription and it can be legally filled. *Id.* Testimony or other evidence to support the proposition that a pharmacist cannot exercise his or her independent judgment in the face of a controlled-substance prescription issued by a physician with superior training would render the corresponding responsibility imposed on registrants under the regulations to be a nullity, and thus, stands in conflict with the regulations and Agency precedent. Testimony to the contrary cannot constitute relevant evidence before a tribunal, such as this one, that lacks authority to evaluate the legal sufficiency of the legislation and regulations it administers.

Dr. Panchal's testimony regarding the number of pain patients he treats in a day provides no evidence which makes any fact of consequence to these proceedings more or less probable. *See* Fed. R. Evid. 401. Thus, these proceedings will not benefit from that testimony.

In its proffered written report of Dr. Zipper, the Respondents also seek to provide his estimation of the percentages of "legitimate" pain patients in and around the Respondents' pharmacies. Once again, this proposed evidence misses the mark of relevance and rebuts no proffered evidence. *See* Fed. R. Evid. 401. The Government has noticed its intent to seek to establish that a patient's unexplained distance from a

dispensing pharmacy and/or treating physician may constitute a red flag that requires resolution prior to the filling of a controlled substance prescription. The number of pain patients dubbed "legitimate" (the meaning of which is not readily divinable from Dr. Zipper's report) adds nothing to the equation. Stated differently, even if it were assumed, *arguendo*, that the percentage of "legitimate" pain patients in the area was somehow knowable, that statistic does not speak to the possibility that such patients exhibited red flags of diversion, or whether such red flags were ignored by the relevant pharmacies. *See* 21 C.F.R. § 1316.59; Fed. R. Evid.. 401.

The expert report of Dr. Zipper also includes a discussion of "guidelines for . . . physicians to help . . . identify risk factors for potential abuse or misuse of [pain] medications by patients." Zipper Expert Report, at 3. Such discussion has no conceivable value to a consideration of the Respondents' corresponding responsibility.

Inasmuch as the proffered testimony of the Respondent's Pain Doctors does not provide sufficient relevant evidence to justify admission, the Government's Motion to Strike is **GRANTED**.

FURTHERMORE, the parties are advised that all testimony and documents regarding the alleged "incentive plan" employed by the Respondents tends to make no fact of consequence to the litigation more or less probable,[13] and will, thus, not be admitted at the hearing. Absent a clear nexus to how such evidence could impact on a registrant's performance of the regulatory corresponding responsibility, this tribunal lacks the expertise, authority, and inclination to evaluate the relative merits of the best business practices of registrant pharmacies. Inasmuch as the Government's proposed evidence in this regard (as proffered) lacks such a nexus, that evidence, as well as Respondent's evidence designed to meet it, will not be admitted.

The Government-proffered testimony that Pharmacists Randy Dwight and Sona Jares told Diversion Investigator Wehrle that they will not fill oxycodone prescriptions tends to make no fact of consequence to the litigation more or less probable,[14] and will, thus, not be admitted at the hearing.

Similarly, all testimony and documents regarding the observations of the

[13] *See* Fed. R. Evid. 401.
[14] *See* Fed. R. Evid. 401

appearance and behavior of Respondents' customers, absent a showing that the particular customer had was dispensed a controlled substance by either of the Respondents adds nothing relevant to the proceedings and will not be admitted.[15]

The noticed report of the Government's purported expert, Paul Doering, expresses opinions based on what appears to be statistical data that has no apparent connection to his profession as a consultant pharmacist. Prop. Gov't Ex. 7. The parties are put on notice that to the extent the Doering report is received in evidence, opinions which are based on areas that stand clearly beyond his expertise will be afforded no weight. In like manner, subject areas that have been excluded by this order (e.g., comparative aggregate amounts of controlled substances ordered, administrative actions and conviction records of physicians, and incentive plans) become no more relevant through the testimony or report of this witness. Additionally, Dr. Doering's report contains a detailed analysis of dosing levels for various controlled substances, but no link to any red flag of any kind, much less to a red flag implicated in the present case. Accordingly, that portion of his report, as well as that portion of the Respondent's purported expert, Dr. Panchal's, report taking issue with that evidence, presents no relevant evidence and will not be considered.

Significant portions of contextual background testimony noticed by the Government to be elicited from Diversion Program Manager Langston and Deputy Assistant Administrator Joseph Rannazzisi appear to be cumulative and will not be received twice. 21 C.F.R. § 1316.59(a).

AND FURTHER, the parties are advised that this order is not intended to address every conceivable evidentiary issue that will be handled during the litigation. Additional evidentiary rulings will certainly be made throughout the course of the hearing, and modifications to this order, borne of evidence received, may require additional latitude regarding evidence admitted to rebut the Government's case, and/or in rebuttal by the Government to the Respondent's case.

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[15] As described above, the corresponding responsibility is violated only when a controlled substance is dispensed in the presence of a red flag. *See supra*. Thus, even assuming that the behavior of a customer may constitute a red flag, the relevance of such behavior to a corresponding responsibility inquiry is contingent upon a showing that controlled substances actually were dispensed to the person displaying the allegedly suspicious behavior. Moreover, characterizations such as "shady" and "sketchy" add nothing to the analysis that must be employed in this adjudication and will not be considered.

Dated: April 13, 2012

JOHN J. MULROONEY, II
Chief Administrative Law Judge

Certificate of Service

This is to certify that the undersigned on April 13, 2012, caused a copy of the foregoing to be delivered via interoffice mail and facsimile to counsel for the Government, Paul Soeffing, Esq., Office of Chief Counsel, Drug Enforcement Administration, 8701 Morrissette Drive, Springfield, Virginia 22152, and a copy of the foregoing was transmitted via facsimile and mailed, postage prepaid, to counsel for the Respondent, John A. Gilbert, Jr., Esq., Hyman, Phelps & McNamara, P.C., 700 Thirteenth Street N.W., Suite 1200, Washington, D.C., 20005.

Shaunta Newby,
Secretary to Chief Judge Mulrooney
Office of Administrative Law Judges